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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,389	11/18/2003	Peter Elsbach	28297/32248C	6372

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EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,389	Applicant(s) ELSBACH ET AL.	
	Examiner Jennifer E. Graser	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/18/03</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____. |
|---|---|

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 10-15, in the reply filed on 2/11/05 is acknowledged.

Specification

2. The disclosure is objected to because of the following informalities:

The status of U.S. Application 09/866,514, in the 'Related Applications' section on page 1, line 15, needs to be updated to reflect that the application is now a U.S. Patent.

The 'Brief Description of the Drawings' on page 5 of the specification must be updated to correctly reflect the Figures in the Drawings, e.g., 'Figure 2' should be amended to recite 'Figure 2A and 2B'; Figure 3' should be amended to recite 'Figure 3A-3D' and Figure 5' should be amended to recite 'Figure 5A-5D'.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: 'DNA encoding bactericidal/permeability increasing proteins'.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite because it the mere recitation of a name, i.e., 'A DNA expression vector comprising a DNA sequence encoding a biologically active recombinant NH2-terminal polypeptide fragment of bactericidal/permeability increasing protein', to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. Further, the name "bactericidal/permeability increasing protein (BPI)" is used for other proteins/protein fragments in the prior art , e.g., rabbit BPI.. The claim must provide any structural properties, such as the nucleic acid sequence or the amino acid sequence of the protein which the DNA encodes, which would allow for one to identify the nucleic acid sequence without ambiguity. The mere recitation of a name does not adequately define the claimed nucleic acid. The actual sequence of the DNA is a critical limitation. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. It is noted that the instant application is granted priority back to an application which did not require the submission of a CRF or paper sequence listing. Accordingly, the sequence may be referred to by Figure number since SEQ identifiers are not included in the instant application.

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Claim 13 is vague and confusing because it is unclear if the sequence recited in the claim represents the entire N_h2-terminal polypeptide fragment the DNA expression vector of claim 10 encodes, or if it is just a partial fragment of the larger sequence.

Clarification is requested.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14 recites that the vector encodes an amino acid sequence from 'residue 1 to about amino acid residue 220 as set out in Figure 5'. However, support for this limitation could not be found. It is noted that in parent application 5,198,541, the language from 'residue 1 to about amino acid residue **210** as set out in Figure 5' was patented. Support was found for that limitation. However, it is not clear where the written support lies for the limitation 'residue 220'. Applicants should point to specific support by page and line number or amend the claim appropriately.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or

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discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 10-15 are rejected under the judicially created doctrine of double patenting over claims 1 and 2 of U. S. Patent No. 5,641,874 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: "Isolated DNA encoding a NH₂-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein" and "A eukaryotic host cell stably transformed or transfected with isolated DNA encoding a NH₂-terminal polypeptide

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bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein”.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

10. Claims 11 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,287,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the instant claims do not specifically recite that the claimed host cells are transfected with nucleotides 124-1491 of the DNA sequence set forth in Figure 5, they do recite that the host cells are transfected with isolated DNA encoding a NH2-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein ~~which is~~”. The fragment recited in the Patent fits under the scope of isolated DNA encoding a NH2-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein” and therefore, it would have been obvious to one of ordinary skill in the art to use the patented fragment to produce a NH2-terminal BPI fragment.

11. Claims 10-15 are rejected under the judicially created doctrine of double patenting over claims 1-4, 6 and 7 of U. S. Patent No. 5,198,541 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

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The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: "Isolated DNA encoding a NH2-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein" and "A eukaryotic host cell stably transformed or transfected with isolated DNA encoding a NH2-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein", "Isolated DNA sequence encoding human bactericidal/permeability increasing protein fragment comprising from **about** residue 1 to about residue 210.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

3. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

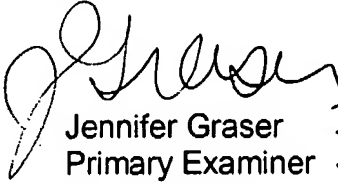
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645

3/21/05